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A comparison of diabetic foot ulcer patients managed in VHA and non-VHA settings

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Abstract—*Objective:* To compare patients with diabetes and new onset foot ulcers treated in Veterans Health Administration (VHA) and non-VHA settings. *Methods*: The treatment of patients with new onset diabetic foot ulcers was prospectively monitored in three VHA and three non-VHA hospitals and outpatient settings until ulcer healing, amputation, or death. *Results*: Of the 302 individuals enrolled in this study, 47% were veterans receiving VHA care. There were no significant differences between veterans and nonveterans in baseline wound classification, diabetes severity, or comorbid conditions. Veterans received significantly fewer sharp debridements, total contact casts, and custom inserts than their nonveteran counterparts, and they had significantly more x-rays, local saline irrigations, IV antibiotics, and prescriptions for bed rest. The percentage of amputations was higher in veterans but did not achieve statistical significance. *Conclusions*: Many commonly held stereotypes of veteran men were not found. Veterans and nonveterans with foot ulcers were similar in terms of health and foot history, diabetes severity, and comorbid conditions. There was considerable variation in treatment of diabetic foot ulcers between VHA and non-VHA care. Yet this variation did not result in statistically significant differences in ulcer outcomes.

Key words: *amputation, diabetes mellitus, diabetic foot, foot ulcers, treatment, wound healing.*

INTRODUCTION

The prevalence of diabetes among veterans receiving Veterans Health Administration (VHA) care has increased to 17 percent, more than double the prevalence in the general population (1). Persons with diabetes have two to four times the risk of coronary artery disease, stroke, and premature mortality than do people without diabetes (2). People with diabetes are also at increased risk for lower limb complications, including ulcers and amputations (3).

Approximately 2 to 3 percent of individuals with diabetes develop one or more foot ulcers each year, and an estimated 15 percent will develop a foot ulcer during

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their lifetime (4–6). Foot ulcers impact the individuals' functional status and quality of life and can lead to amputation. Optimal treatment of diabetic foot ulcers has been reported to include a multidisciplinary team, glycemic control, nutritional support, offloading strategies, treatment of infection, ensuring adequate blood flow, adequate debridement, topical wound care, and education (7). The extent to which these practices are routinely employed in treating ulcer patients in inpatient and outpatient settings is not known.

A VA case-control study identified that foot ulcers preceded 84 percent of lower limb amputations in persons with diabetes (8,9). In VHA facilities between 1989 and 1998, there were 70,200 lower limb amputations. The major indication for these amputations was diabetes (63 percent) followed by atherosclerotic vascular disease (23.6 percent) (10). While there has been a reduction in amputations in veterans without diabetes during this decade, similar progress is less evident in veterans with diabetes. Treatment and outcomes for diabetic ulcers has received little research attention in the VHA. Therefore, the purpose of this paper is to describe characteristics, treatments, and outcomes for VHA and non-VHA patients with new onset foot ulcers.

METHODS

This prospective study was conducted at three VHA hospital and outpatient facilities (one each in the northwest, southwest, and southern US) and three non-VHA inpatient and outpatient facilities (one each in the southern and north central US and Switzerland) between October 1994 and April 1996. Research assistants (RAs) at all sites were trained on the standardized study protocol, data collection methods, study instruments, and computerized data entry programs. At each study, site investigators and RAs developed and maintained an inpatient and outpatient surveillance network to identify eligible patients.

Eligible patients were aged 40 to 85 years, reported a history of diabetes documented in medical records, and presented with one or more untreated foot lesions resulting in functional interruption of the cutaneous barrier at or below the malleoli. Data were collected on up to three ulcers per patient, though analysis is based on the most severe ulcer. Patients were excluded if lesions were superficial, above the malleolus, secondary to surgery, required surgery within 72 hours of presentation, or if they had made two or more outpatient visits for care of the lesion. Patients were also excluded if they refused surgery for the lesion, planned foot care outside the study facility, or could not provide informed consent.

At enrollment RAs observed and documented the foot care provided by clinicians. The study did not impose treatment protocols; rather RAs recorded the routine treatment practices of clinicians. Data collection included demographic, health, diabetes and foot history, patient function, activity, and quality of life. Lesions were photographed and scored for severity using the Seattle Wound Classification System (11). (Categories 1–3 represent superficial, nonulcerated minor lesions, preulcerative soft tissue infections, and partial thickness ulcers; categories 4–6 represent full thickness ulcers; and categories 7–9 represent ulcers with involvement of tendon, ligament, joint, capsule, bone, infection, and gangrene.) At each follow-up visit, RAs were present to characterize, measure, and trace the patient's lesion; document the foot care provided; and report healing progress. All patients were followed until one of three outcomes occurred: healing, amputation, or death.

This descriptive analysis utilizes data on the most severe foot ulcer enrolled, covering the ulcer episode from baseline to resolution. Data were analyzed using SAS (12). Frequencies were computed for all study variables. Statistical comparison of categorical variables between VHA and non-VHA users used chi-square test statistics and two sample t-tests. All tests were two-tailed and used a significance level of $p<0.05$.

RESULTS

There were 302 consecutive patients who met study eligibility criteria, 142 veterans (47 percent) and 160 nonveterans (53 percent). **Table 1** shows the average age was of borderline significance between veterans and nonveterans (63.3 years *versus* 60.7 years). A higher proportion of veterans were male (99.3 percent *versus* 53.8 percent). A significantly lower proportion of veterans than nonveterans were Caucasian, and more veterans were Hispanic (36.6 percent *versus* 23.1 percent), in part because two VHA facilities were located in the southern/southwestern US. A higher but not statistically significant proportion of study veterans than nonveterans were married or living with a significant other.

The self-care practices of veterans and nonveterans showed no significant difference in average body mass

Table 1.
Baseline demographic and clinical characteristics of veteran and nonveteran participants in the Diabetes Ulcer Outcome Study.

	VHA patients (n=142)	Non-VHA patients (n=160)	Total population (n=302)
Demographic findings			
Average age (years)	63.3±9.4	60.7±13.7	61.9±11.9
% Male	99.3	53.8	75.1
Race/ethnicity			
% White (non-Hispanic)	50.7*	68.1	59.9
% Hispanic	36.6	23.1	29.5
% All other	12.7	8.8	10.6
% Married/living together	56.0	52.5	54.2
Self-care findings			
Average HbA_{1c}	8.69±2.0	9.32±2.2	9.03±2.1
% Daily blood glucose self-monitoring	56.3*	34.4	44.6
Assistant with foot care**			
% Spouse or living companion	48.2	39.0	43.3
% Family or friend	20.7	26.4	18.4
% None	34.7	30.7	33.7
% Daily foot exam	77.8	66.9	72.0
Smoking**			
% Current smoker	19.9	20.1	20.0
% Ever smoked	75.9	54.7	64.7
% Never smoked	24.1	45.3	35.3
Past year alcohol use			
% All other	12.7	8.8	10.6
% None	67.4	57.9	62.3
% <=1–5 drinks per week	28.3	32.7	29.1
% >=6 drink/week (heavier)	3.5	9.4	6.7
Health history findings			
Diabetes type			
% type 2 diabetes	81.5*	66.9	73.7
% type 1 diabetes	6.7	11.7	9.34
% Unsure	11.8	21.4	17.0
Diabetes duration			
% 0 to 5 years	17.0	15.7	16.3
% 6–15 years	37.8	35.3	36.4
% 16 or more years	45.2	49.0	47.2
% Sensory neurotherapy symptoms	72.8	67.5	70.0
Lower limb health history**			
% Prior leg or foot ulcer	63.4	56.2	59.6
% Prior peripheral vascular bypass	17.8	11.7	14.5
% Prior lower limb amputation	35.9	27.5	31.5
Severity scores			
Average diabetes severity score (Range 0–6)	2.0±1.2	1.8±1.2	1.9±1.2
+Average comorbidity score	0.39±0.7	0.34±0.6	0.36±0.6

* Chi-square or t-test $p<0.05$ for comparison between VA and non-VA patients
** Categories not mutually exclusive or exhaustive

index. Veterans averaged lower glycemic levels (HbA_{1c}) than nonveterans, and significantly more veterans reported daily self-blood glucose monitoring than nonveterans (66.3 percent *versus* 34.4 percent). Veterans were more likely than nonveterans to receive assistance with their foot care from a spouse or significant other, though this finding was not statistically significant. While this was also the chief source of foot care assistance for

nonveterans, 26 percent of nonveterans also received care from family and friends compared to 21 percent of veterans. Veterans conducted more daily foot exams than nonveterans, although this difference did not achieve statistical significance. While there were no differences in current smoking practices, significantly more veterans had a smoking history than nonveterans (75.9 percent *versus* 54.7 percent). A majority of both veterans and nonveterans regularly consumed no alcohol in the past year, and there were fewer heavy drinkers comparing veterans to nonveterans (3.5 percent *versus* 9.4 percent).

Self-reported health history findings in **Table 1** show a significantly higher proportion of veterans had type 2 diabetes than did nonveterans (81.5 percent *versus* 66.9 percent). Of nonveterans, 21.4 percent were unsure of their diabetes type, compared to 11.8 percent of veterans. There was no statistically significant difference between the VHA and non-VHA patients in self-reported sensory neuropathy. Compared to nonveterans, veterans had a higher frequency of prior leg or foot ulcers (63.4 percent *versus* 56.2 percent), peripheral vascular bypass procedures (17.8 percent *versus* 11.7 percent), and prior lower limb amputations (35.9 percent *versus* 27.5 percent). These differences were not statistically significant. Scores measuring six diabetes complications and three serious comorbid conditions showed no significant differences between groups.

Table 2 shows the only statistically significant difference in physical foot findings between veterans and nonveterans was in fungal toenail disease (63 percent *versus* 33.8 percent). Over three-fourths of the study participants were insensate to the monofilament and 25 percent of all participants had one or more foot deformities. Pitting edema was observed in 35 percent to 45 percent of study participants.

The ulcer site in one-fourth of the veterans and one-third of nonveterans was the plantar midfoot. A significantly higher proportion of ulcers was located on the dorsal toes in veterans compared to nonveterans (36.6 percent *versus* 21.3 percent). Ulcers were classified by the Seattle Wound Classification and grouped by severity into categories 1–3, 4–6, 7–9. There were no significant differences for ulcer severity between veterans and nonveterans.

The diagnostic and treatment variations between veterans and nonveterans are presented in **Table 3**. This

Table 2.
Baseline foot characteristics in Diabetes Ulcer Outcome Study patients.

Variable	VHA patients (n=142)	Non-VHA patients (n=160)	Total population (n=302)
Foot observations, %			
Insensate 5.07 monofilament	78.9	78.5	78.6
Bunion present	20.9	14.8	17.6
Hallux limitus present	25.6	24.2	24.8
Fixed claw toes present	14.2	20.1	17.4
Charcot collapse	20.9	14.8	17.6
Pitting edema of foot or leg	45.0	35.6	40.0
Fungal disease of toenails	63.0*	33.8	47.5
Paronychia	2.9	1.3	2.0
Ulcer location, %			
Plantar midfoot	25.3*	35.6	30.8
Dorsal toes	36.6	21.3	28.5
Plantar toes	17.6	28.1	23.2
Dorsum	16.9	5.6	10.9
Heel	3.5	9.4	6.6
Seattle wound classification, %			
Classes 1–3	14.8	18.1	16.6
Classes 4–6	64.8	56.9	60.6
Classes 7–9	20.4	25.0	22.8

* Chi-square or t-test $p<0.05$ for comparison between VA and non-VA patients

Table 3.
Diagnostic and treatment practices ever used during the first Diabetes Ulcer Outcome Study episode.

	VHA patients (n=142)	Non-VHA patients (n=160)	Total population (n=302)
Lesion assessment +			
% Radiography	59.4*	46.3	52.4
% Culture pre- or postdebridement	39.4	30.6	34.7
Wound cleansing debridement +			
% Local saline irrigation	40.9*	26.3	32.9
% Betadine	35.7	26.9	30.8
% Soaking	26.6*	3.8	13.8
% Whirlpool	3.1*	13.3	8.6
% Sharp debridement	79.9*	91.9	86.3
Antibiotics +			
% Oral	62.6	59.5	60.9
% Intravenous	38.2*	24.7	31.0
Dressings +	17.6	28.1	23.2
% Soft dressing (gauze, kerlix, etc.)	86.6	89.4	88.1
% Hydrogels	14.8	11.3	12.9
% Alginates	14.1	17.5	15.9
% All other	32.4*	13.8	22.5
Offloading strategies +			
% Off-the-shelf inserts	14.8	13.1	13.9
% Custom inserts	35.2*	47.5	41.7
% Therapeutic shoes	27.5	36.3	32.1
% Custom shoes	24.7	26.3	25.5
% Healing shoe or sandal	49.3	43.8	46.4
% Bivalve and other boots/casts	16.9	23.8	20.5
% Total contact cast	6.3*	17.5	12.3
% General cushion/minimum off-loading	14.1	13.8	13.9
% Bed rest	39.4	22.5	30.5
Assistive devices +			
% Cane	19.0*	29.4	24.5
% Crutches	17.6	21.9	19.9
% Walker	9.2*	23.8	16.9
% Wheelchair	29.6	38.8	34.4

* Chi-square or t-test $p<0.05$ for comparison between VA and Non-VA patients
+ Categories not mutually exclusive or exhaustive

table describes inpatient and outpatient diagnostic and treatment practices ever used during the ulcer episode. Radiography was used significantly more often to assess lesions in veterans than in nonveterans (59 percent *versus* 46 percent). Veterans' lesions were cultured more often pre- or postdebridement than were lesions in their nonveteran counterparts. Wound cleansing and debridement strategies showed significant differences between the study groups. Veterans were significantly more likely to have their wounds irrigated with saline and have a prescription for soaking than were nonveterans. Veterans were significantly less likely to receive whirlpool treatment (3.1 percent *versus* 13.3 percent) and sharp debridement (79.9 percent *versus* 91.9 percent) than were nonveterans.

Intravenous antibiotics were prescribed significantly more often for veterans than for nonveterans (38.2 percent *versus* 24.7 percent), even though the frequency of hospitalization was similar between groups. There were no significant differences between use of gauze and kerlix dressings, hydrogels, and alginates. When nonstandard dressings were grouped, they were used significantly more often with veterans than with nonveterans (32.4 percent *versus* 13.8 percent).

Offloading weight strategies prescribed at any time during the ulcer episode showed significantly fewer custom inserts (35.2 percent *versus* 47.5 percent) and total contact casts (6.3 percent *versus* 17.5 percent) in veterans compared to nonveterans. However bed rest was prescribed significantly more often for veterans than for nonveterans (39.4 percent *versus* 22.5 percent). Assistive devices were prescribed for many individuals. Nonveterans received significantly more canes and walkers than veterans and were more frequently prescribed crutches and wheelchairs, although these latter findings were not statistically significant.

Table 4 describes the inpatient and outpatient health care utilization revealing that 37.8 percent of veterans and 34.4 percent of nonveterans were hospitalized at least once. The proportion of veterans hospitalized two or more times was 9.6 percent compared to 7.5 percent in nonveterans. The average number of outpatient visits was 5 in veterans and 4.8 in nonveterans.

There were no statistically significant differences in ulcer outcomes or time to outcome. **Table 4** shows healing was achieved in 81 percent of study patients. There were 15 patients (5 percent) who died prior to ulcer resolution. In all cases deaths were unrelated to the foot ulcers. Amputation frequency was higher, though not significant, in veterans than in nonveterans (18.3 percent *versus* 10.6 percent). Of the amputations performed, the frequency of minor amputations was higher in veterans than in nonveterans (89 percent *versus* 77 percent).

DISCUSSION

This multisite study compared patient treatments and outcomes between 302 veterans and nonveterans with diabetic foot ulcers who were prospectively followed in inpatient and outpatient facilities during an entire ulcer episode. Despite veterans' reputation for high disease comorbidity and disease severity, study veterans and nonveterans were similar in terms of demographics, health history, lesion characteristics, diabetes severity, and disease comorbidity. No significant differences were observed between ulcer outcomes and time to outcome by veteran status. Many veteran stereotypes were not observed in this study population. For example, veterans had better glycemic control, improved self-blood glucose monitoring, a low frequency of drinking, and support of a spouse, family member, or friend to assist in foot care. The notable demographic and health history exceptions were the high proportion of males and persons with type 2 diabetes in the VHA population. Less than 10 percent of veterans are females, therefore males comprise the vast

Table 4.
Health care utilization and outcomes for foot ulcer patients in the Diabetes Ulcer Outcome Study.

	VHA patients (n=142)	Non-VHA patients (n=160)	Total patients (n=302)
Health care utilization			
% Inpatient care	37.8	34.4	36.4
Hospitalizations			
% One	28.2	26.9	27.4
% >=Two	9.6	7.5	8.4
Average number of outpatient visits	5.0±5.2	4.8±4.4	4.9±4.8
Outcomes			
% Healed (n=244)	76.1	85.0	80.8
% Amputation	18.3	10.6	14.2
% Minor	89	77	83.7
% Major	11	24	16.3
% Death (n=15)	5.6	4.4	5.0
Average weeks to healing	10.9±10.5	10.6±13.6	10.7±12.3
Average weeks to amputation	11.6±16.4	13.8±15.1	12.5±15.8
Average weeks to death	12.8±8.5	18.2±15.4	15.3±12.1

majority of veterans. Diabetes mellitus is an exclusion criterion for military enlistment, thus the only military discharges in persons with type 1 diabetes are in those developing type 1 diabetes after military enlistment.

Veterans had lower blood glucose levels than nonveterans. However, the average HbA_{1c} levels even among veterans (8.7 percent) was still above the American Diabetes Association recommended level (13). The significantly higher frequency of self-blood glucose monitoring among veterans may have contributed to their improved glycemic control compared to nonveterans. Guidelines for management of patients with diabetes were developed by the Veterans Health Administration and encourage providers to work with patients to individualized glycemic goals based on life expectancy, presence of microvascular complications, and family history of microvascular complications (14). Elevated HbA_{1c} levels have been associated with increased risk of amputation in several analytic studies (15–17).

While nonveterans had a higher frequency of plantar midfoot and plantar toe lesions, veterans had more dorsal toe and dorsal foot lesions. There may have been differences due to shoes worn by men and women. Lesion site may contribute to the differences observed in offloading weight strategies since different modalities are employed depending on whether the lesion is located on a weight-bearing area. Offloading weight and/or removing pressure is indicated for virtually all foot ulcers, but there is little agreement on optimum strategies to achieve this goal.

The more frequent use of total contact casts in nonveterans is expected in part since total contact casts are not indicated for dorsal lesions. In addition, availability and expertise required using total contact casts varied widely across study sites. Some providers consider canes and walkers "offloading devices," however, there is no agreement on the effectiveness of these assistive devices for offloading weight. These strategies were used significantly more often in non-VHA than VHA sites.

Radiography was used significantly more often at VHA than non-VHA sites (59.4 percent *versus* 46.3 percent). The American College of Foot and Ankle Surgeons recommends an initial imaging study for detection of osteomyelitis, osteolysis, fractures and dislocations in neuropathic arthropathy, and calcification in medium and small vessels or with soft-tissue gas (18). The high frequency of x-rays may accompany the increased use of IV antibiotics at VHA sites even though there were no significant differences between VHA and non-VHA patients in wound severity. Other explanations for higher numbers of x-rays include practice style, academic *versus* nonacademic setting, and time since completion of medical training.

Soaking and whirlpool treatments are controversial. Some research recommends against these therapies in persons with diabetes due to the increased likelihood of tissue maceration and spread of infection. However, 25 percent of VHA patients and 4 percent of non-VHA patients were exposed to soaking and 13.3 percent of non-VHA and 3.1 percent of VHA patients received one or more whirlpool treatments.

All wounds are colonized with potentially pathogenic organisms; thus the diagnosis of infection in a foot ulcer is based on clinical rather than microbiological criteria (19). Pre- and postdebridement cultures were used in 35 percent of study patients overall. These cultures could assist in antibiotic treatment choices or could confound treatment by isolation of nonpathologic, superficial bacteria. There was a significant difference in use of IV antibiotics between VHA and non-VHA patients. IV antibiotics would be expected in the treatment of limb-threatening infections. Since the ulcer classification, frequency of hospitalization, and number of hospitalizations were similar between veteran and nonveteran groups, this finding is not easily explained. There was no significant difference in the use of oral antibiotic between VHA and non-VHA sites and the combined use over the ulcer episode was approximately 60 percent. The ADA Consensus Development Conference on Diabetic Wound Care suggests that antibiotic therapy in noninflamed neuropathic ulcers is associated with increased cost of care, potential adverse effects, and an increased likelihood of microorganisms developing resistance; thus the prophylactic use of antibiotics for noninfected lesions is not supported (19).

Based on the evidence used for the ADA Foot Ulcer Consensus Panel, the panel concluded there was no significant benefit in velocity of diabetic foot ulcer healing by dressing type (19). The standard soft dressing (gauze and kerlix) was used by approximately 88 percent of participants. Variation in other dressing types was expected as different dressings are indicated at different times during the wound healing cycle. Dressing selection is guided by wound type, drainage, patient factors, and costs. Veterans did use significantly more nonstandard dressings than nonveterans (32.4 percent *versus* 24.7 percent).

The diabetic patient with a prior history of foot ulcers is at risk for ulcer recurrence. In this study,

approximately 60 percent of ulcer patients reported a prior foot ulcer. Foot ulcer recurrence was assessed in a study by Mantley comparing patients with an initial foot ulcer and two ulcer recurrences to diabetic patients who had only one ulcer and no recurrences over a two-year interval. He reported greater peripheral sensory neuropathy and poor diabetes control in the ulcer recurrence group. Members of the ulcer recurrence group waited longer from observing a foot ulcer to seeking care, had higher glycemic levels, and consumed more alcohol than their counterparts without ulcer recurrence (20).

There are several potential limitations to this study. The number of study participants, 302, is not large and may have limited our ability to detect the impact of treatments on ulcer outcomes. The Seattle Foot Ulcer Classification was used to estimate foot ulcer severity (11). Foot ulcer classification schemes are imperfect and difficult to apply uniformly. Simple classification schemes that predict outcomes are needed.

In conclusion, foot ulcers and amputations are a serious public health and clinical problem. A wide range of treatment modalities is available for their management (7,19,21). The differences in patient demographics, health history, and treatments in VHA and non-VHA patients were not significantly associated with differences in ulcer outcomes. Additional randomized clinical trials are needed with larger numbers of patients to determine the most effective combinations of preventive and treatment strategies to protect the lower limbs of veterans and nonveterans with diabetes.

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REFERENCES

1. Reiber GE, Boyko EJ, Manyard C, Koepsell T. Diabetes in the VA. Diabetes Care (*Submitted*).
2. Harris MI. Summary. In: Harris MI, editor. Diabetes in America, 2nd ed. Bethesda, MD: National Institute of Health. National Institute of Health Publication No. 95-1468, 1995; p. 1–13.
3. Reiber GE, Boyko E, Smith DG. Lower extremity ulcers and amputations in individuals with diabetes. In: Harris MI, editor. Diabetes in America, 2nd ed. Bethesda, MD: National Institute of Health. National Institute of Health Publication No. 95-1468, 1995; p. 409–27.
4. Ramsey SD, Newton K, Blough D, McCulloch DK, Sandhu N, Reiber GE, Wagner EH. Incidence, outcomes, and cost of foot ulcers in patients with diabetes. Diabetes Care 1999;22:382–7. 1992;152:610–6.
6. Palumbo PJ, Melton LJ. Peripheral vascular disease and diabetes. In: Harris MI, Hammam RF, editors. Diabetes in America. Bethesda, MD: National Institutes of Health, National Institutes of Health Publication No. 85-1468, 1985: p. XV, 1–21.
7. Millington TJ, Norris TW. Effective treatment strategies of diabetic foot wounds. Family Practice 2000;S40–8.
8. Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation: basis for prevention. Diabetes Care 1990;13;513–21.
9. Reiber GE, Pecoraro RE, Koepsell TD. Risk factors for amputations in patients with diabetes mellitus. Ann Intern Med 1992;117:97–105.
10. Mayfield JA, Reiber GE, Maynard C, Czerniecki JM, Caps MT, Sangeorzan BJ. Trends in lower limb amputation in the Veterans Health Administration, 1989–1998. J Rehabil Res Dev 2000;37:23–30.
11. Pecoraro RE. Diabetic skin ulcer classification for clinical investigations. Clinical Materials 1991;257-62.
12. SAS/Stat Software V6.12, SAS Institute, Inc. Cary, NC, 1997.
13. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. Diabetes Care 2001;24:33s–43s.
14. VHA-DoD. Diabetes guidelines for management of patients with diabetes mellitus. http://www.va.gov/health/diabetes/DiabetesGuidelines.pdf.

15. Moss S, Klein R, Klein B. The 14-year incidence of lower-extremity amputations in a diabetic population. Diabetes Care 1999;22;951–9.
16. Selby JV, Zhang D. Risk factors for lower extremity amputations in persons with diabetes. Diabetes Care 1995;18:509–16.
17. Lehto S, Pyorala K, Ronnemaa T, Laakso M. Risk factors for predicting lower extremity amputations in patients with NIDDM. Diabetes Care 1996;19:607–12.
18. American College of Foot and Ankle Surgeons. Diabetic foot disorders—a quick reference guide. Data Trace Publishing Company, 2001.
19. American Diabetes Association. Consensus development conference on diabetic foot wound care. Diabetes Care 1999;22:1354–60.
20. Mantley I, Foster AVM, Spencer S, Edmonds ME. Why do foot ulcers recur in diabetic patients? Diabetic Medicine 1999;16:245–9.
21. Mason J, O'Keeffe C, Hutchinson A, McIntosh A, Young R, Booth A. A systematic review of foot ulcer in patients with type 2 diabetes mellitus. II: treatment. Diabetic Medicine 1999;16:889–909.